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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,209	09/28/2005	Denise M. Baker	2006.0260001/EKS/PAC	8322

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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
09/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,209	BAKER ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/28/05, 9/29/08, 6/11/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,16,23,26 and 31-40* is/are pending in the application.

4a) Of the above claim(s) *3-7,23,26,31 and 33-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,16 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice to Comply with the sequence rules.

DETAILED ACTION

1. Applicant's amendment filed 9/28/05 and responses filed 9/29/08 and 6/11/09 are acknowledged and have been entered.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is required under 37 C.F.R. 1.821(d) to amend the specification to list the appropriate SEQ ID NOS for sequences disclosed in the specification (for example, at [00241], [00355], [00358], [00359], [00361], [00364], [00366], [00367], Tables 6-29, brief description of the drawings for Figures 1-4).

3. Applicant's election with traverse of species of (i) identifying from a particular antigen of a particular infectious agent variants of a class I MHC peptide epitope 8-11 amino acid residues in length, each variant comprising primary anchor residues of the same HLA class I binding motif, determining whether each of said variants comprises conserved, semi-conserved or non-conserved non-anchor residues in comparison to each of the remaining variants, and identifying a variant which comprises only conserved non-anchor residues in comparison to at least one remaining variant, in the response filed 6/11/09 is acknowledged.

The basis for the traversal is of record in the said response on pages 1-3, briefly that a search of the subject matter of species (i)-(iv) together would not be a serious burden on the Examiner.

However, unity of invention, not restriction practice as per MPEP 803, is applicable in national stage applications submitted under 35 U.S.C. 371. Thus, establishing serious burden is not required in the application of 371 practice.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 1 and 2 read upon the elected species.

Upon consideration of the prior art, examination is being extended to include the species HIV recited in instant claims 16 and 32.

Claims 1, 2, 16 and 32 are currently being examined.

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, for example, at [00174]. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 16 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 32 are indefinite in the recitation of "spp." Because it is not clear what is meant. (In addition note that "spp" after "Histoplasma" does not have a period).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1, 2, 16 and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by De Groot *et al* (Immunology and Cell Biology, 2002, 80: 255-269, of record).

De Groot *et al* teach comparing the sequence of 8-11-mer peptides across strains of infectious agents such as HIV-1 to identify broadly conserved (cross-clade) epitopes (that contain motifs for binding a particular MHC class I molecule, that is, anchor residues, both primary and secondary), and further teach including in the method, the allowance of amino acid substitutions at non-anchor positions (see entire reference).

Although the reference does not explicitly teach that the non-anchor residues have only conservative substitutions, the reference does teach that the peptides have the anchor residues for binding a particular MHC class I molecule and that the peptides are conserved, meaning that the amino acid residues at non-anchor positions are identical or conservative substitutions. In addition, the art reference method inherently teaches that the non-anchor positions are assessed for conserved, semi-conserved or non-conserved amino acid residues. Therefore, the claimed process appears to be the same or similar to the process of the prior art absent a showing of differences. Since the Patent Office does not have the facilities for examining and comparing the process of the instant invention to those of the prior art, the burden is on Applicant to show an unobvious distinction between the process of the instant invention and that of the prior art. See In re Best, 562 F2d 1252, 195 USPQ 430 (CCPA 1977).

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1, 2, 16 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Groot *et al* (Immunology and Cell Biology, 2002, 80: 255-269, of record).

De Groot *et al* teach comparing the sequence of 8-11-mer peptides across strains of infectious agents such as HIV-1 to identify broadly conserved (cross-clade) epitopes (that contain motifs for binding a particular MHC class I molecule, that is, anchor residues, both primary and secondary), and further teach including in the method, the allowance of amino acid substitutions at non-anchor positions (see entire reference).

De Groot *et al* do not *explicitly* teach that the non-anchor residues have only conservative substitutions.

However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have selected for conservative substitutions at non-anchor residues because those residues may serve as T cell contact residues, and also because the art reference teaches that amino acid residues other than the primary anchor residues may also promote or interfere with binding.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
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August 4, 2009

/G.R. Ewoldt/
Primary Examiner, Art Unit 1644